DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 20, 2015

Tenscare Ltd.
% Linda Stamschor
US Agent
Akos (Meddiquest)
17957 615th Street
Kellogg, MN 55945

Re: K142506
Trade/Device Name: Tenscare KegelFit
Regulation Number: 21 CFR 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: November 6, 2014
Received: March 11, 2015

Dear Linda Stamschor,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142506

Device Name
Tenscare KegelFit

Indications for Use *(Describe)*
KegelFit is a non-implanted muscle stimulator designed to treat female stress urinary incontinence.
It applies stimulation to the pelvic floor muscles to improve strength and support.
The KegelFit is intended for OTC sale.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section5
510(k) Summary

Date of Summary prepared: 7th April 2015

I **Submitter** : Tenscare Ltd
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Address of American Representative:

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II Submitted Device:

Generic name: Pelvic Floor Stimulator
Trade name: TensCare KegelFit
Common name: KegelFit Pelvic Floor Exerciser
Classification name: Stimulator, Electrical, Non-implantable, for Incontinence – Title 21, Code of Federal Regulations Sec.876.5320 ProCode: 78 KPI
Device Classification: Class **II**

III Predicate Devices:

510(k)	Name	Product Code	Class	Use	Manufacturer
Primary Predicate					
K141158	Apex	KPI	II	OTC	InControl Medical, LLC 3225 Gateway Road, Ste. 250 Brookfield, WI 53045 USA
Secondary Predicate					
K103698	itouch Sure Pelvic Floor Exerciser	KPI	II	Prescription	Tenscare Ltd 9 Blenheim Road, Epsom,Surrey, KT19 9BE, UK

IV Device Description:

The KegelFit is a hand-held, home-use device designed to treat female stress urinary incontinence. The device is supplied with a vaginal two electrode stimulation probe (Trainer). The trainer connects to the control unit by cable and plug and is inserted into the vagina by the end user. Electrical stimulation is delivered via stainless steel electrodes on the trainer to induce a contraction of the pelvic floor muscles. Muscle stimulation is used to train and strengthen the pelvic floor muscles in a controlled manner. Muscle stimulation is used to improve the ability of muscles to hold a contraction for an extended period of time and is a treatment for urinary incontinence. During a session, stimulation is delivered to specific muscles to encourage their contraction. This contraction strengthens the muscles and also helps the end user recognize which muscles to activate during self-directed contractions. The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

The device is battery powered single channel home use neuromuscular stimulation. Electrical stimulation is delivered via stainless steel electrodes on the inflatable probe to induce a contraction of the pelvic floor muscles. Muscle stimulation is used to train and strengthen the pelvic floor muscles in a controlled manner. Muscle stimulation is used to improve the ability of muscles to hold a contraction for an extended period of time and is a treatment for urinary incontinence. During a session, stimulation is delivered to specific muscles to encourage their contraction. This contraction strengthens the muscles and also helps the end user recognize which muscles to activate during self-directed contractions. The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

The unit is intended for home use by the patient, and is designed with simplicity and ease of use in mind. It has two preset treatment programs, a preset treatment timer, a compliance monitor, and open circuit detectors.

V The intended use of the device:

KegelFit is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.

The intended use and indications for use of the new device are the same as those of the predicate device Apex K141158

KegelFit for over-the-counter use was evaluated for safety in two ways:-

-Ability to self-diagnose and identify whether contraindication apply was established by detailed comparison with labeling and instructional packaging of the predicate device Apex K141158

-Ability to use effectively was established by analysis of customer reviews over 4 years and 13758 OTC sales of the predicate device itouch Sure K103698 through Amazon UK.
The user manual was revised three times over this period in response to customer feedback and to comply with EN60601-1-11.

The device labeling and packaging (which includes a box, detailed instructions for use, and laminated quick reference guide) allow the end user to accurately self-diagnose and use the product to treat stress urinary incontinence.

VI Equivalence Comparison to the Predicate Devices

Electrical muscle stimulation is the technological principle for both KegelFit and the predicate devices, Apex (K141158) and itouch Sure (K103698). It is based on the use of the electrical muscle stimulator to strengthen the pelvic floor muscles.

Table 6 below summarizes the shared and unique technological elements between the KegelFit, itouch Sure, and Apex devices. The technology, engineering, performance and user interface for KegelFit is substantially equivalent to the predicate devices.

Intended Use has been changed from prescription to OTC and from all types of incontinence only, and the available settings and labeling have been modified to allow for this change. The intended use, labeling and user interface for KegelFit is substantially equivalent to the predicate device Apex.

The KegelFit is a relabelled version of the itouch Sure(K103698). The components, electronics, and accessories are identical. The display and software have been modified in line with the change in Intended Use. The physical differences between the two versions of the product are:

	KegelFit	Itouch Sure	Explanation
Program name	TRAIN	STRES	To be less technical, and stress the need for Kegel exercises.
Program name	X	URGE	Removed as Urge and Mixed are not included in the Intended Use
Program name	X	MIXED	Removed as Urge and Mixed are not included in the Intended Use
Treatment Timer	Default 20 min , 10 min selectable	Default 20 min, up to 60 min selectable	Only adverse report received was of over-use leading to muscle cramping. IFU amended. Longer treatment times removed.
Keypad	On/Off Colour coded		ON/OFF buttons colour coded to clarify operation

The KegelFit is substantially equivalent to the itouch Sure, which has been approved for home and hospital use on prescription.
Safety and effectiveness for home use with professional instruction is therefore established.

The KegelFit packaging and instructions for use are substantially equivalent to that of the Apex for the relevant criteria:-

- How well the lay user can self-select themselves as being appropriate users
- Whether the lay user can understand all indications, contraindications, warnings and precautions, and be able to identify whether they are within any contraindicated group.

This Substantial Equivalence is established by detailed comparison of labeling in Section 12. The KegelFit uses identical or substantially equivalent wording, frequency of use, and positioning of Intended Audience, Contraindications, Warnings and Cautions.

The final comparison is that of the ability of the lay user to be able to apply the treatment safely and correctly according to the instructions for use without training.
TensCare presents analysis of Customer Reviews from OTC sales of 13,768 units of itouch Sure through Amazon UK and 21 customer questionnaires sent to 120 users of itouch Sure as evidence that the lay user finds the device easy to use and the instructions easy to follow.

Table 6. Substantial Equivalence Comparison Table

Features/ Function	A KegelFit K142506	B Itouch Sure	C Apex K141158	Comparison A/B	Impact on safety and performance	Comparison A/C	Impact on safety and performance
Intended Use An explicit description of all clinical functions performed by the device,		The Itouch Sure is a non-implanted electrical stimulator indicated for use in the treatment of female urinary incontinence. It applies electrical stimulation to the pelvic floor musculature and surrounding structures					
Indications for Use Explain when the device is to be clinically used and the intended patient population	KegelFit is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.	The itouch **Sure** is indicated for acute and ongoing treatment of stress, urge or mixed urinary incontinence and where the following results may improve urinary control: • Improvement of urethral sphincter closure • Strengthening of pelvic floor muscles • Inhibition of the detruser (bladder) muscle through reflexive mechanisms	Apex is a non-implanted muscle stimulator designed to treat female stress urinary incontinence. It applies stimulation to the pelvic floor muscles to improve strength and support.	Substantially equivalent	None: Both devices apply electrical stimulation to strengthen the pelvic floor muscles, as supported by literature, see Section20.1 Clinical Evaluation Report	Identical	None:
Features/ Function	A Kegelfit	B Itouch Sure	C Apex K141158	Comparison A/B	Impact on safety and performance	Comparison A/C	Impact on safety and performance
Primary Function	Delivery of electrical stimulation	Delivery of electrical stimulation	Delivery of electrical stimulation	Identical	None	Identical	None
Warnings or Precautions	(See product labeling)		(See product labeling)			Substantially Equivalent	The Warnings and Cautions were based on the predicate Apex which was validated through human factors and Usability Testing. Only minor changes were made to allow for the technical differences between the products
Contra-indications Explain when the device is not to be clinically used	• Do not use if you are pregnant. • Do not use if you are attempting to get pregnant • Do not use if you have a cardiac demand pacemaker or implanted defibrillator. • Do not use if you have symptoms of active urinary tract infection, vaginal	**Contraindications** Should not be used if you have any of the following conditions: • If you are pregnant or trying to become pregnant • If you have a heart pacemaker or a heart rhythm problem • If you have: - An active urinary tract infection - Infections or lesions in the area of electrode placement	• Do not use if you are pregnant • Do not use if you are attempting to get pregnant • Do not use if you have a cardiac demand pacemaker or implanted defibrillator • Do not use if you have symptoms of active urinary tract infection, vaginal infections, or localized lesions	Substantially equivalent	None	Identical	None

	infections, or localized lesions • Do not use if you have a diagnosis of extra-urethral or overflow incontinence • Do not use if you have severe urine retention • Do not use if you have poor sensation in the pelvic region • Do not use if you have cognitive disabilities, i.e.; Alzheimer's disease or dementia • Do not use if you are unable to properly insert the Trainer • Do not use if you have active pelvic cancer • Do not use it you have an intestinal clamp • You must be 6 weeks post pelvic surgery or vaginal childbirth to use this device • Do not use this device for diagnostic purposes or critical patient monitoring • This device is not (external) defibrillator-proof	- History of urinary retention or post-void residual volume greater than 200cc - Diminished sensory perception - Inability to understand the directions for use or operate the device correctly • If you have been diagnosed or treated for cervical, or any pelvic, cancer - Recent history of vaginal bleeding between menstrual periods • If you have, or have had epilepsy If any discomfort occurs when inserting the probe, consult your treating physician.	• Do not use if you have a diagnosis of extra-urethral or overflow incontinence • Do not use if you have severe urine retention • Do not use if you have poor sensation in the pelvic region • Do not use if you have cognitive disabilities, i.e.; Alzheimer's disease or dementia • Do not use if you are unable to properly insert the device per instructions • Do not use if you have active pelvic cancer • Do not use if you have an intestinal clamp • You must be 6 weeks post-pelvic surgery or vaginal childbirth to use this device • Do not use this device for diagnostic purposes or critical patient monitoring • This device is not (external) defibrillator-proof				
Features/ Function	A Kegelfit	B Itouch Sure	C Apex K141158	Comparison A/B	Impact on safety and performance	Comparison A/C	Impact on safety and performance
Labeling Summary Clarity to insure safer or more effective use	User Manual Retail Box Contraindications insert Device controls		User Manual Retail Box Contraindications insert Device controls	Substantially equivalent	None: The operating instructions part of the user manual is based on the predicate, itouch Sure,with references to Urge and Mixed programs removed. Illustrations and Quick Start guide were added to further improve usability	Substantially equivalent	None. See comparison table of the self-diagnosis, contraindications and warnings.
Environ-mental Specific-ations	For indoor use only	For indoor use only	For indoor use only	Identical	None	Identical	None
Power Source	2 AA Alkaline battery	2 AA Alkaline battery	4 AAA Alkaline battery	Identical	None:	Substantially	None

						equivalent	Battery insertion was validated through analysis of customer reviews
Method of line current isolation	N/A (battery)	N/A (battery)	N/A (battery)	Identical	None	Identical	None
Patient leakage current	N/A (battery)	N/A (battery)	N/A (battery)	Identical	None	Identical	None
Number of Output Modes	Two	Four	One	Substantially Equivalent.	None Matches alteration in Intended Use	Substantially equivalent	None. Customer reviews indicate no difficulty in using more than one program
Number of output channels	1	1	1	Identical	None	Identical	None
Regulated current or voltage?	Regulated current	Regulated current	Regulated voltage	Identical	None	Substantially equivalent	None Both regulated current and voltage have been shown to be safe and effective
Firmware controlled?	Yes	Yes	Yes	Identical	None	Identical	None
Automatic Overload Trip?	No	No	No	identical	None:	identical	None:
Automatic No-Load Trip?	Yes	Yes	No	identical	None:	Substantially equivalent	None: KegelFit offers additional user protection
Automatic Shut Off?	Yes	Yes	No	Identical	None	Substantially Equivalent.	Apex user must switch off at end of session
Patient Override Control?	Yes	Yes	No	Identical	None	Substantially Equivalent.	None. Customer reviews indicate no difficulty in using this facility
Indicator Display • On/Off Status • Low Battery	 Yes Yes	 Yes Yes	 Yes (via display illumination) No	Identical	None	Substantially equivalent	None: Kegelfit offers additional information. Message is easily understood and customer reviews indicate no difficulty in using this facility
Display - Voltage/Current Level?	Yes LCD	Yes LCD	Yes combination of two LEDs	Identical	None	Substantially equivalent	LCD readout is much simpler than combination of static and flashing LEDs
Waveform,	Bi-phasic	Bi-phasic	Monophasic, alternating polarity,	Identical	None	Substantially equivalent	None. Both waveforms are approved in predicate devices
shape	Rectangular at positive	Rectangular at positive	square pulse	Identical	None	Substantially equivalent	
Frequency • Mixed • Stress • Urge	 - Hz 50 Hz -Hz	 20 Hz 50 Hz 10 Hz	 50 Hz	Substantially equivalent	None	Substantially equivalent	None. Both predicate devices have been approved as safe and effective.

• Tone	35 Hz	35Hz					
Pulse width • Mixed • Stress • Urge • Tone	- 300µs - 250µs	250µs 300µs 250µs 250µs	- 200 µs - -				No special requirements demonstrated for home use
Time On +ramp • Mixed • Stress • Urge • Tone	- 7 seconds on - 5 seconds on	7 seconds on 7 seconds on 7 seconds on 5 seconds on	- 1 second on - -	Substantially equivalent	Programs removed in line with change in intended use	Substantially equivalent	None. All settings have been approved for use on predicate devices
Time Off • Mixed • Stress • Urge • Tone	- 10 seconds off - 6 seconds off	10 seconds off 10 seconds off 10 seconds off 6seconds off	- 2 seconds off - -	Substantially equivalent	Programs removed in line with change in intended use	Substantially equivalent	None. All settings have been approved for use on predicate devices
Total Session Time	Default 20 minutes Adjustable to 10 minutes. Instructions for Kegel exercises provided separately	Default 20 minutes Adjustable to 10,20,30,45,60 and 90 minutes	Total session time of 10-15 minutes • 5-10 minutes electrical stimulation • 5 minutes self-directed contraction (recommended)	Substantially equivalent	None. Longer session times removed in response to customer feedback	Substantially equivalent	None
Compliance* with 21 CFR 898 Cable and lead requirements.	Yes	Yes	N/A	Identical	None	Substantially Equivalent.	None No leads in Apex device
Max output voltage (500Ω)	45V	45V	34.2 V	Identical	None	Substantially equivalent	None. Both predicate devices have been approved as safe and effective.
Max output current (500Ω)	90mA	90mA	68.2 mA	Identical	None	Substantially equivalent	
Maximum phase charge (500Ω)	18.6 µC	18.6 µC	13.6 µC	Identical	None	Substantially equivalent	Apex is monophasic, so net charge=max charge
Electrode surface area	8.58 cm_2	8.58 cm_2	5.88 cm_2	Identical	None	Substantially equivalent	None. Both predicate devices have been approved as safe and effective. No special requirements for home use
Max current density	10.46 mA/cm_2	10.46 mA/cm_2	11.6 mA/cm_2	Identical	None	Substantially equivalent	
Max average power density (500Ω)	5.84 mW/cm_2	5.84 mW/cm_2	3.95 mW/cm_2	Identical	None	Substantially equivalent	
Dimensions (Insertion Unit)	Trainer Weight: 0.7 oz (20 gm) Length:2.87" (73 mm) (inserted part) Width:1.1" (28mm) dia (widest point)	Trainer Weight: 0.7 oz (20 gm) Length:2.87" (73 mm) (inserted part) Width:1.1" (28mm) dia (widest point)	Overall Insertion Unit: 12.2"x 2.5"x 4.0"	Identical	None	Substantially equivalent	None
Control housing material	ABS plastics	ABS plastics	N/A	Identical	None	N/A	
Insertion material	ABS plastics Stainless steel	ABS plastics Stainless steel	Silicone, plastics Stainless steel	Identical	None	Substantially equivalent	
Packaging or Expiration	N/A	N/A	1 year for insertion unit	Identical	None	Substantially equivalent	None: Expiration dating is not

Dating							needed based on the stability of the materials chosen.
Sterilization	N/A	N/A	N/A	Identical	None	Identical	None
Features/ Function	A Kegelfit	B Itouch Sure	C Apex K141158	Comparison A/B	Impact on safety and performance	Comparison A/C	Impact on safety and performance
Operational Method: Clinical Use e.g., ambulatory use, home use	Home use, Over-the-counter	Clinic or Home use, under direction of physician	Home use, Over-the-counter	Substantially equivalent	None: An over-the-counter indication does not impact safety because the stimulation is controlled by the end user per end user response. Safety features are built into the design of the device for the maximum output, overload and short circuit, and automatic shut-off.	Identical	None
Patient Interaction: Functions Controllable: An explanation of how the device interacts with the patient.	The end user can control the electrical stimulation levels and the starting and stopping of each session. However, the device will stop on its own once the session is normally completed.	The patient can control the electrical stimulation levels and the starting and stopping of each session. However, the device will stop on its own once the session is normally completed.	The end user can control the electrical stimulation levels and the duration of the stimulation session.	Substantially equivalent	None. Option to increase treatment time has been removed to improve simplicity of use. User feedback indicated that some users were tempted to over-use to speed recovery	Substantially equivalent	None: Control is by pushbutton in both devices. Customer Reviews show that the additional buttons in the KegelFit are clear and easy to understand. KegelFit also displays intensity, treatment time remaining, and low battery warning.
Patient Interaction: Programming Capability Whether the device can be programmed and to what extent	Electrical stimulation levels are set by the end user End user can choose between two stimulation programs. End user can reduce the session timer	Electrical stimulation levels are set by the end user End user can choose between four stimulation programs. End user can reduce or increase the session timer	Electrical stimulation levels are set by the end user	Substantially equivalent	None. Both stimulation programs are proven safe and effective. Reduced timer setting is the same as that recommended for the Apex.	Substantially equivalent	None. Although Kegelfit offers a choice of programs, both are effective for stress incontinence.
Patient Interaction: Operator Requirements Knowledge or training required of the operator,	Intended as part of a complete therapy program with physician coaching. No special knowledge or training; instruction manual provided	Over-the-counter device. No special knowledge or training required; instruction manual provided	Over-the-counter device. No special knowledge or training required; instruction manual provided	Substantially equivalent	None: The KegelFit device has fewer optional settings. In both cases, no special knowledge or training is required.	Identical	None
Software Level of Concern	Moderate	Moderate	Moderate	Identical	None	Identical	None

VII Testing Summary

The following performance testing was provided in support of the substantial equivalence. The testing for KegelFit included software, electrical safety, biocompatibility and clinical. KegelFit successfully passed all testing.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, We determine that the level of concern of the new device KegelFit is Moderate; the decision-making process is as follows:

Prior to mitigation of hazards, a failure of the Software Device cannot result in death or serious injury, either to a patient or to a user of the device. Therefore not level of concern is not Major.

But, prior to mitigation of hazards, a failure of the Software Device can result in Minor injury, such as electrical shock, either to a patient or to a user of the device.

We determine that the level of concern of the new device KegelFit is Moderate.

Electrical Safety Testing:

Electrical safety testing was conducted on KegelFit. The device complies with the IEC 60601-1 and IEC60601-1-11 standards for safety

EMC testing:

The KegelFit has been tested to EN60601-1-2:2007 and found to be suitable for use in domestic establishments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Biocompatibility Testing:

The same vaginal electrode is used as with the itouch Sure
Body material:
Acrylonitrile-Butadiene-Styrene copolymer (ABS) GE MG47
Conductor Material: Stainless steel

The biocompatibility evaluation for the itouch Sure vaginal electrode (KegelFit Trainer) was conducted in accordance with International Standard ISO 10993:2009 biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity and ISO 10993:2002 biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity. See section 14.

Clinical Testing:

A clinical literature evaluation was conducted to provide evidence of the safety and efficacy of electrical stimulation for the treatment of female stress urinary incontinence. See section 20.1

Labelling Comparison: The Labelling is substantially equivalent to that of the predicate device Apex for self diagnosis and identification of contraindications and to the predicate device itouch Sure for operating instructions.

A detailed comparison of labeling between the KegelFit and the predicate device Apex was conducted to assess the safety of the KegelFit device for over-the-counter use. The objectives of this comparison were to:
1) determine if a subject can self-identify as having stress urinary incontinence using package labeling
2) self-limit usage if a contraindication is present

Customer Review Analysis:

An analysis of customer reviews of the predicate device itouch Sure from 13758 OTC sales in the EU was used to determine whether the subject can safely use the KegelFit device using only the instructions for use (IFU) provided. A questionnaire was sent to a further 120 Ebay UK OTC customers.

Risk Management Summary

KegelFit has been designed according to EasyMed's internal procedures with traceability between the design inputs, design outputs, verification and validation activities. KegelFit has been evaluated for risks according to EasyMed's internal procedures based on ISO 14971. The risks associated with KegelFit were reduced to as low as possible and the risk/benefit analysis was acceptable.

Conclusion

The non-clinical data supports the safety of the device, and the hardware and software verification and validation demonstrates thatKegelFit performs as intended in the specified use conditions.

The clinical literature evaluation, as well as the technological comparison to the predicate device, supports the use of electrical stimulation as an effective treatment of stress urinary incontinence in women.

Both KegelFit and the predicate device Apex are intended for over-the-counter use. A comparison of labeling and instructions was completed to support the safety of the product labeling for self-diagnosis and use.

An analysis of Customer Reviews of OTC sales in the EU of the predicate device itouch Sure was completed to support the Usability of the device without training. In addition, customer questionnaires were sent to 120 users of itouch Sure who purchased OTC through ebay UK, and 21 responses were received and analysed.The data included within this submission supports the use of KegelFit for over-the-counter as safe and effective. The KegelFit unit is substantially equivalent to the predicate devices and any differences between the devices do not pose any new questions of safety and effectiveness.

Submitted times: This is the first submission to FDA for this new device